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EXAMINER

WHITEMAN, BRIAN A

ART UNIT

PAPER NUMBER

1635

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/380,203

Applicant(s)

DE LA MONTE ET AL.

Examiner

Brian Whiteman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3,5,6,10-13,35-37,39-47 and 49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 39,40-43,49 is/are allowed.
- 6) ☒ Claim(s) 1-3,5,6,10-13,35 and 44-47 is/are rejected.
- 7) ☒ Claim(s) 36 and 37 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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## **DETAILED ACTION**

### **Final Rejection**

Claims 1-3, 5, 6, 10-13, 35-37, 39-47 and 49 are pending examination.

Applicants' traversal, the amendment to claims 1, 39, 45, and 49, the cancellation of claims 38 and 48 in paper no. 31 filed 7/7/03 is acknowledged and considered.

### ***Specification***

The disclosure remains objected to because of the following informalities: the status (e.g., pending, abandoned, patented US Patent No.) of US applications listed on pages 14 and 20-21 is missing.

In paper no. 31, filed on 7/7/03, applicants request that this ground of objection be held in abeyance until the remaining issues in this application are resolved.

The objection to the disclosure remains for the reasons set forth above.

### ***Claim Objections***

Applicant's arguments, see paper no. 31, filed on 7/7/03, with respect to objection have been fully considered and are persuasive. The objection of claim 1 has been withdrawn because of the amendment to claim 1.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 3, 5, 6, 10-13, and 35 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 2, 3, 5, 6, 10-13, and 35, as best understood, are readable on a genus of a DNA molecule of SEQ ID NO: 1 or a DNA molecule which is at least 90% homologous to SEQ ID NO: 1 wherein said DNA molecule is under control of a heterologous neuro-specific promoter, and wherein said DNA molecule codes for a protein that has an activity of AD7c-NTP when over-expressed in neuronal cells, wherein the genus of DNA molecules is not claimed in a specific biochemical or molecule structure that could be envisioned by one skilled in the art at the time the invention was made.

The specification contemplates a genus of DNA molecules that code for a protein having the activity of SEQ ID NO: 1, which induces neuritic sprouting, nerve cell death, nerve cell degeneration, neurofibrillary tangles, and/or irregular swollen neurites in a host which expresses the DNA sequence (page 18, lines 28-30 and page 20, lines 1-2). The specification provides sufficient description of SEQ ID NO: 1 and a nucleotide sequence encoding the amino acid sequence set forth in SEQ ID NO: 2. The specification provides sufficient description for a DNA molecule that codes for an AD7c-NTP protein as set forth in SEQ ID NO: 2 when over-expressed in neuronal cells. The art of record teaches that there is a variation within the genus of the claimed DNA molecules. The art of record further teaches that one nucleotide change in a DNA molecule could result in the loss of its biological activity. The essential nucleotides

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required for an activity of AD7c-NTP are absent from the specification. The specification does not disclose a known correlation between the structure (primary structure) and function of SEQ ID NO: 1 to a genus of claimed DNA molecules. More specifically, the specification does not disclose what amino acids are required for description of a representative number of DNA molecules with 90% homology to SEQ ID NO: 1. The specification does not provide sufficient description of a genus of DNA molecules with 90% homology to SEQ ID NO: 1 that codes for a protein that has an activity of AD7c-NTP when over-expressed in neuronal cells. It is not apparent that on the basis of the applicants' disclosure an adequate written description of the invention defined by the claims requires more than a mere statement that it is part of the claimed invention and reference to potential methods and/or molecular structures of molecules that are essential for the genus of DNA molecules that must exhibit the disclosed biological functions as contemplated by the specification.

It is not sufficient to support the present claimed invention directed to a genus of a DNA molecule of SEQ ID NO: 1 or a DNA molecule which is at least 90% homologous to SEQ ID NO: 1 wherein said DNA molecule is under control of a heterologous neuro-specific promoter, and wherein said DNA molecule codes for a protein that has an activity of AD7c-NTP when over-expressed in neuronal cells. The claimed invention as a whole is not adequately described if the claims require essential or critical elements, which are not adequately described in the specification and which is not conventional in the art as of applicant's effective filing date. Claiming a genus of DNA molecules which is at least 90% homologous thereof, that must possess the biological properties as contemplated by applicant's disclosure without defining what means will do so is not in compliance with the written description requirement. Rather, it is an

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attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)).

Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998). The skilled artisan cannot envision the detailed structure of a genus of a DNA molecule, which displays at least 90% homology to SEQ ID NO: 1 that must exhibit the contemplated biological functions, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the structures and/or methods disclosed in the as-filed specification. Thus, in view of the reasons set forth above, one skilled in the art at the time the invention was made would not have recognized that applicant was in possession of the claimed invention as presently claimed.

Applicant's arguments filed 7/7/03 have been fully considered but they are not persuasive because in view of the specification and the art of record at the time the application was filed, the specification does not satisfy the written description requirement to reasonably clarify to those skilled in the art, as of the effective filing date, applicants were in possession of the claimed invention.

The rejection remains for the reasons of record and because applicants' arguments were already addressed in previous office actions (see Non-Final Rejection filed on 4/8/03 and Final Rejection filed on 2/9/02).

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Claims 1, 2, 3, 5, 6, and 35 remain rejected under 35 U.S.C. 112, first paragraph, because the specification is enabling only for a DNA construct, which comprises the DNA molecule of SEQ ID NO: 1 or a DNA molecule comprising a nucleotides sequence encoding the amino acid sequence set forth in SEQ ID NO: 2, wherein said DNA molecule is under control of a heterologous neuro-specific promoter and does not reasonably provide enablement for a DNA molecule which is at least 90% homologous to SEQ ID NO: 1 wherein said DNA molecule is under control of a heterologous neuro-specific promoter, and wherein said DNA molecule codes for a protein that has an activity of AD7c-NTP when over-expressed in neuronal cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 10-13 and 44-47 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in In re Wands, 858 F.2d 731, 8USPQ2d 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claimed invention is directed to a DNA construct, which comprises the DNA molecule of SEQ ID NO: 1 or a DNA molecule which at least 90% homologous thereto, wherein said DNA molecule is under control of a heterologous neuro-specific promoter, and wherein said

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DNA molecule codes for a protein that has an activity of AD7c-NTP when over-expressed in neuronal cells and a method for screening a candidate drug that is potentially useful for treating Alzheimer's Disease using a host cell transformed with said DNA construct. The field of the invention lies in making a DNA molecule which at least 90% homologous to SEQ ID NO: 1.

The specification contemplates a genus of DNA molecules comprising a nucleotide sequence with 90% homology to SEQ ID NO: 1 or having activity of AD7c-NTP. The specification teaches isolation of AD7c-NTP (SEQ ID NO: 1) from a cDNA library. The specification contemplates that DNA molecule which are 90% homologous to SEQ ID NO: 1 may be isolated from cDNA libraries of human and animals. On pages 45-46 and 48-50 of the specification, assays are contemplated that can be used to identify DNA molecules that encode for proteins that possess activity of AD7c-NTP.

In view of In Re Wands Factors, the specification teaches one skilled in the art how to make a DNA molecule comprising the nucleotide sequence set forth in SEQ ID NO: 1 or comprising a nucleotide sequence encoding the amino acid sequence set forth in SEQ ID NO: 2. The specification does not provide sufficient guidance or factual evidence for one skilled in the art to practice the full scope of the claimed invention. The specification does not disclose which nucleotides of the claimed DNA molecule is considered essential for one skilled in the art to make a representative number of DNA molecules with 90% homology to SEQ ID NO: 1. In view of the art of record and the as-filed specification, it is apparent that one skilled in the art would be able to determine a DNA molecule with 90 percent homology to SEQ ID NO: 1. However, the specification does not provide sufficient guidance and/or factual evidence for one skilled in the art to determine without an undue amount of experimentation to determine if the



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nucleic acid sequence with at least 90 percent homology to SEQ ID NO: 1, would exhibit the same biological function of SEQ ID NO: 1 (observed activity when the sequence is over-expressed in neuronal cells). Since, the relationship between a sequence of a peptide and its tertiary structure (i.e. its activity) are not well understood and are not predictable (e.g. see Ngo et al. The protein folding problem and tertiary structure prediction, 1994, Merz et al (ed.) Birkhauser, Boston, MA pp. 433 and 492-495 and Chiu et al., *Folding and Design*, 1998, pp. 223-228, cited on a prior 892), it would required undue experimentation for one skilled in the art to arrive at other DNA molecules with 90% homology to SEQ ID NO: 1 and having SEQ ID NO: 1 activity when over-expressed in neuronal cells. In addition, in *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991), the court ruled that a claim to a large genus of possible genetic sequences encoding a protein with a particular function that needs to be determined subsequent to the construction of the genetic sequences may not find sufficient support under 35 U.S.C. 112, first paragraph, if only a few of the sequences that meet the functional limitations of the claim are disclosed and if undue experimentation would be required of one skilled in the art for the determination of other nucleotide sequences that are embraced by the claims. This is the case here. In other words, since it would require undue experimentation to identify other DNA molecules with at least 90% identity to SEQ ID NO: 1 and retaining the biological activity of SEQ ID NO: 1, it certainty would require undue experimentation to make their corresponding DNA and, therefore, one skilled in the art would not enabled to make a genus of DNA molecules with 90% homology to SEQ ID NO: 1.

With respect to the *in vitro* methods contemplated in claims 10-13 and 44-47, the as-filed specification does not provide sufficient guidance for one skilled in the art to make and/or use

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the claimed methods. The specification contemplates an *in vitro* drug screening system. The specification teaches cloning AD7c-NTP into a Lac-Switch expression vector and stably transforming neuronal cells in vitro with said vector. However, the specification does not teach how to distinguish true negatives from false negative or true positives from false positives using the method contemplated in the claimed methods. The specification uses the cDNA of AD7c-NTP, thus most, if not all of the transcriptional and translation control sequences of AD7c-NTP gene are removed from the nucleotide sequence. The control sequences (e.g., heterologous neuro-specific promoter) contemplated by the claims are not the same control sequences of the endogenous AD7c-NTP because the sequences are from another gene. The suppression or prevention of expression of the protein coded by the DNA construct in b(i) would reflect interaction with the control sequence and result in false positives/false negatives. Thus, the result of using a promoter/control sequence from another gene would not reflect the activity of the endogenous AD7c-NTP gene.

Furthermore, the specification does not teach how to distinguish an increase in degradation of the protein coded for by the DNA construct from a decrease expression of the protein coded for by the DNA construct. For example, if the candidate drug inhibits expression from the heterologous sequence then the decrease of protein expression would result in both b(i) and b(ii). The specification does not teach an assay for how to distinguish between b(i) and b(ii). A decrease in level of the protein could result from degradation of the protein or lack of expression from the promoter. A decrease in expression would not reflect interaction of AD7c-NTP protein with the candidate drug. The specification does not provide sufficient guidance or factual evidence for one skilled in the art to determine if detection of one of the following from

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step (b)(i)-(iii) is caused by the drug interacting with the non-coding sequence (e.g., promoter); with the AD7c-NTP cDNA, or independently with another gene product in the cultured cells.

The art of record is absent for teaching how to determine whether the mechanism caused by the candidate drug is the result of interacting with the promoter, the cDNA, or another protein in the cultured cells. Thus, it would take one skilled in the art an undue amount of experimentation to practice the claimed methods.

In conclusion, the as-filed specification and claims coupled with the art of record at the time the invention was made only provide sufficient guidance and/or evidence to reasonably enable one skilled in the art to make a DNA construct, which comprises the DNA molecule of SEQ ID NO: 1 or a DNA molecule comprising a nucleotides sequence encoding the amino acid sequence set forth in SEQ ID NO: 2, wherein said DNA molecule is under control of a heterologous neuro-specific promoter and not for the full scope of the claimed invention.

Applicants' arguments filed 7/7/03 with respect to claims have been fully considered but they are not persuasive.

In view of the In Re Wands Factors, the as-filed specification does not provide sufficient guidance or factual evidence for one skilled in the art to make a DNA construct, which comprises a DNA molecule which is at least 90% homologous to SEQ ID NO: 1, wherein said DNA molecule is under control of a heterologous neuro-specific promoter, and wherein said DNA molecule codes for a protein that has an activity of AD7c-NTP when over-expressed in neuronal cells. The specification provides a nucleotide sequence set forth in SEQ ID NO: 1 and the amino acid sequence set forth in SEQ ID NO: 2 and an assay to determining if a nucleotide

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sequence possess a biological activity of AD7c-NTP set forth in SEQ ID NO: 1. However, the specification does not provide sufficient guidance or evidence for what nucleotides of SEQ ID NO: 1 the amino acid sequence set forth in SEQ ID NO: 2 are required to retain a biological activity of SEQ ID NO: 1. The art of record teaches the unpredictability of predicting the biological activity of a protein based on its nucleotide sequence. In view of the breadth of the claims it would take one skilled in the art an undue amount of experimentation to make a genus of DNA molecules with at least 90% homology to SEQ ID NO: 1 and having AD7c-NTP activity.

The statements (see pages 12 and 14 of applicants' traversal, filed on 7/7/03) indicate that a representative number of species of the claimed genus of polynucleotide sequences were not disclosed in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, to make and use a genus of claimed polynucleotide sequences without an undue amount of experimentation. It is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of an invention in order to constitute adequate enablement, e.g. Genetech Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366, 42, USPQ2d 1001, 1005 (Fed. Cir. 1997).

Furthermore, with respect to the assertion that the specification (see page 19, lines 3-15 of the as-filed specification) provides sufficient guidance for making a genus of DNA molecules with 90% homology to SEQ ID NO: 1 and having AD7c-NTP activity.

The court in Enzo 188 F.3d at 1374, 52 USPQ2d at 1138 states:

It is well settled that patent applications are not required to disclose every species encompassed by their claims, even in an unpredictable art. However, there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed.

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In re Vaeck, 947 F.2d 48, 496 & n.23, 30 USPQ2d 1438, 1445 & n.23 (Fed. Cir. 1991)(citation omitted). Here, however, the teachings set forth in the specification provide no more than a “plan” or “invitation” for those of skill in the art to experiment...; they do not provide sufficient guidance or specificity as to how to execute that plan. See Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993); In re Wright, 999 F.2d...[1557], 1562, 27 USPQ2d...[1510], 1514. [Footnote omitted].

On this record, it is apparent that the specification (See page 19) provides no more than a plan or invitation in view of the unpredictability of predicting biological activity of nucleotide sequence based on its nucleotides set forth in the art of record and the lack of guidance provided by the as-filed specification for making a nucleotide sequence with 90% homology to SEQ ID NO: 1 to use further experimentation to determine if the sequence possesses SEQ ID NO: 1 activity, for those skilled in the art to experiment with any DNA molecule with 90% homology to SEQ ID NO: 1 as intended by the as-filed specification at the time the invention was made.

See also Genetech Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366, 42, USPQ2d 1001, 1005 (Fed. Cir. 1997)

(“Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable the public to understand and carry out the invention.”)

In view of the art of record and the lack of guidance provided by the specification; the specification does not provide reasonable detail for making a genus of DNA molecules which are 90% homologous to SEQ ID NO: 1 having the biological activity of SEQ ID NO: 1 other than SEQ ID NO: 1 and a nucleotide sequence encoding the amino acid sequence set forth in SEQ ID NO: 2, and it would take one skilled in the art an undue amount of experimentation to reasonably extrapolate from the assertion in the specification to the full breadth of the claimed invention. Therefore, the as-filed specification is not enabled for the full breadth of the claimed invention.

With respect to the argument directed to the 112 first paragraph enablement rejection for the method claims (see pages 16-19), the argument is considered and is not found persuasive.

The assertion (page 17) that, “no evidence or scientifically sound arguments have been presented,” is not found persuasive. Other than the assertion, the applicants provide no factual evidence to support the assertion. Applicants are directed to the reasons set forth under the 112 first paragraph enablement for the method claims. More specifically, the specification uses the cDNA of AD7c-NTP, thus most, if not all of the transcriptional and translation control sequences of AD7c-NTP gene are removed from the nucleotide sequence. The control sequences (e.g., heterologous neuro-specific promoter) contemplated by the claims are not the same control sequences of the endogenous AD7c-NTP because the sequences are from another gene. The suppression or prevention of expression of the protein coded by the DNA construct in b(i) would reflect interaction with the control sequence and result in false positives/false negatives. The specification does not teach one skilled in the art how to distinguish between true positives and negatives/false positive and negatives, respectively. Thus, one skilled in the art would not know any more about the compound then before the assay was performed. See Enzo 188 F.3d at 1374, 52 USPQ2d at 1138 and Genetech Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366, 42, USPQ2d 1001, 1005 (Fed. Cir. 1997). The result of using a promoter/control sequence from another gene would not reflect the activity of the endogenous AD7c-NTP gene.

With respect to the second assertion (page 18) that, “There are numerous methods that were well known in the art at the time the application that could have distinguish between (i) and (ii),” the assertion is not found persuasive for the reasons of record. The specification does not

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contemplate using any method to distinguish between (i) and (ii). See Enzo 188 F.3d at 1374, 52 USPQ2d at 1138. It is acknowledged that the specification teaches assays for measuring AD7c-NTP expression *in vitro*. However, the examples (pages 41-45) do not use a vector comprising a heterologous neuro-specific promoter operably linked to a nucleic acid encoding AD7-cNTP. In addition, the specification does not teach one skilled in the art how to reasonably extrapolate from using a nucleic acid encoding AD7c-NTP not under control of a heterologous promoter or using AD7c-NTP for studying *in vitro* expression to distinguishing an increase in degradation of the protein coded for by the DNA construct from a decrease expression of the protein coded for by the DNA construct in the claimed methods.

Furthermore, with respect to the third assertion (pages 18 and 19) that, “a candidate drug that causes at least one of (i), (ii), or (iii), regardless of what it interacts with or its mechanism of action, is a drug that is potentially useful of the treatment or prevention of Alzheimer’s Disease, neuroectodermal tumors, malignant astrocytomas, or glioblastomas”, is not found persuasive. In addition, the assertion is not found persuasive for the reasons of record. In addition, if the mechanism of action is the result of the interaction with the heterologous promoter, then the drug may not exert an effect directly or indirectly for treating or preventing any of the diseases listed above. The specification does not teach how determine if the result of a drug resulted from the interaction of the protein from the cDNA or the heterologous promoter. See Enzo 188 F.3d at 1374, 52 USPQ2d at 1138 and Genetech Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366, 42, USPQ2d 1001, 1005 (Fed. Cir. 1997).

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***Conclusion***

Claims 39-43 and 49 are in condition for allowance because the claims are free of the prior art of record.

Claims 36 and 37 remain objected to as being dependent upon a rejected base claim (claim 1), but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775.



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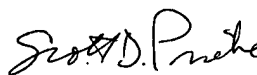
The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman  
Patent Examiner, Group 1635

  
SCOTT D. PRIEBE, PH.D  
PRIMARY EXAMINER